

REMARKS

Claims 2-6, 8-13 and 15-25 are pending in the present application and all said claims stand rejected. Applicants herein amend independent claims 6, 13 and 19 and dependent claim 15. Applicants earnestly solicit entry and favorable consideration of the amendments and remarks presented herein.

Applicants assert that the minor amendments to the preamble of the independent claims and the corresponding confirmatory amendments to the body of said claims do not raise new issues requiring search and were not earlier presented because the posture of the application did not require same.

Claim Rejections Under 35 U.S.C. §103(a)

In the Office Action, the Examiner rejected claims 2, 4-6, 8, 9, 11-13, 15, and 17-19 under 35 U.S.C. §103(a) as being unpatentable over an International application to Prutchi et al., WO 99/37360 ("Prutchi") in view of U.S. Pat. No. 6,209,764 to Hartlaub et al. ("Hartlaub").

Applicants respectfully suggest that the Prutchi and Hartlaub fail to address the unique problem addressed by the present invention; namely, detection of a interference signal characteristic of magnetic resonance imaging (MRI) interference. No portion of either Prutchi or Hartlaub addresses the problem solved by the instant invention. Furthermore, neither Prutchi nor Hartlaub appear to provide any motivation, suggestion or teaching regarding an MRI-specific – and tolerant – pacing schema.

For example, an excerpt from Hartraub reveals the "problem solved" by the invention therein; namely:

When such an external signal induces a current in the conductive loop and in turn the electrically excitable tissue, the user may experience pain and uncontrollable motor responses. Thus, this induced current is unwanted, and the present invention limits this unwanted current. (emphasis added.)

Thus, unlike the present invention, which deals only with magnetic resonance imaging ("MRI") and not the genus of electromagnetic interference ("EMI"), Hartraub fails to contemplate a solution wherein pacing persists, albeit with an MRI-tolerant sensing scheme. To further magnify this fact, Applicants herein amend independent

claims 6, 13 and 19 to eliminate the fact that the mode-switch of the present invention is not triggered by typical, relatively low-energy EM interference. That is, although abundantly clear from the specification and drawings the present invention is directed to MRI-based cardiac activity sensing. For example, the acronym "EMI" does not even appear anywhere in said specification. The present mode switch is intended to continue a physiologically-based cardiac sensing regimen, not to protect a subject from currents (as is the focus of Hartraub).

As taught in the written description of the present application, the presence of MRI interference can be inferred from a signal characteristic, detected by a Hall Effect sensor, antenna or the like that strongly correlates only to the patient's proximity to an operating MRI system. To wit,

The Hall Effect sensor 500 may be capable of detecting magnetic fields having magnetic field strengths in the range of about 0.2 Tesla (2000 Gauss) to about 10 Tesla (100,000 Gauss). A magnetic field having a magnetic field strength above a threshold of about 0.17 Tesla (1700 Gauss) may be taken as an indication of the magnetic resonance imaging (MRI) scan.

Alternatively, and/or additionally, any other type of sensor capable of detecting other properties of the electromagnetic fields that may be produced during the magnetic resonance imaging (MRI) scan may be used by the detector 440 to detect the presence of the high static magnetic field. For example, other fields associated with the MRI scan, such as a static gradient magnetic field, a variable gradient magnetic field with a frequency of up to about 5 kHz, radio-frequency pulses with a frequency of up to about 50 MHz, or a variable magnetic field with a frequency of about 64 MHz, may be detected by the detector 440.

Thus, the amended claims stand amended herein to include appropriate claim elements, supported by the specification as filed, directed to detection of an operating MRI system.

In addition, the Examiner rejected claims 3, 10 and 16 under 35 U.S.C. §103(a) as being unpatentable over Prutchi in view of Hartlaub as applied above in further view of a pre-grant published application to Silvian et al.; namely, US-2002/0072769 ("Silvian") or U.S. Pat. No. 5,882,304 to Ehnholm et al. ("Ehnholm").

Applicants herewith incorporate the above-noted deficiencies of Hartraub and further suggest that the proposed combination fails to render the claimed invention, as

amended, obvious as neither reference contemplates identifying a magnetic field characteristic of an operating MRI scanning system and responding with an "MRI-safe" cardiac pacing and cardiac sensing modality. Since claim 3, 10 and 16 recite the foregoing limitations, Applicants respectfully suggest that the present ground of rejection stands traversed and should be withdrawn.

As to both obviousness-type claim rejections, Applicants assert the following. In connection with combining references to support an assertion of obviousness, it is well established that the Examiner bears the burden of establishing a prima facie case of obviousness. In re Oetiker, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce" the claimed invention. In re Chu, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995). A prima facie case of obviousness is established only when this burden is met.

The burden is still on the Examiner even when the Examiner relies upon a single reference. "Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference." In re Kotzab, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000).

In the case of In re Lee, 61 USPQ2d 1430 (Fed. Cir. 2002), the Federal Circuit stated: "This factual question of motivation is material to patentability, and [can] not be resolved on subjective belief and unknown authority." Id. at 1434. Determination of patentability must be based on evidence, id. at 1434, and the Examiner provided none: no references pertaining to aggregation or averaging were cited, no official notice was taken, no evidence of any kind was presented. The Examiner's failure to present an evidentiary basis for the decision is clearly a legal error. Id. Assertions such as "common knowledge and common sense," even if assumed to derive from the Examiner's expertise, are not evidence, and conclusory statements do not fulfill the Examiner's obligation to make an evidentiary record. Id. at 1434-35; In re Dembiczak, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

If indeed the elements were known in the art, then the Examiner ought to present evidence to support that conclusion. In re Lee, 61 USPQ2d at 1435 ("[W]hen they rely

on what they assert to be general knowledge to negate patentability, that knowledge must be articulated and placed on the record."). The failure to do so renders the Examiner's rejection arbitrary, capricious and unreasonable. See id. at 1434. The Examiner may not arbitrarily, capriciously and unreasonably deny a claim by a mere declaration of obviousness without a supporting evidentiary record.

The Examiner presented no evidence of any suggestion or motivation to modify the prior art to arrive at the claimed invention. Nor has the Examiner presented any evidence that the recited elements are known in the art. The record consists exclusively of conclusory statements by the Examiner, which are not evidence and which cannot support rejections under 35 U.S.C. § 103.

For at least these reasons, the Examiner has failed to establish a *prima facie* case for non-patentability of Applicants' pending claims under 35 U.S.C. § 103(a). Withdrawal of this ground of rejection is hereby earnestly and respectfully requested.

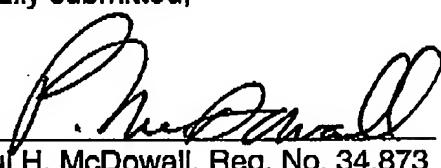
CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 13-2546. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Respectfully submitted,

Date: 25 Oct. 04

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